GOLDMAN ISMAIL TOMASELLI BRENNAN & BAUM LLP

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Daniel C. Burke
Bernstein Liebhard, LLP
10 East 40th Street, 28th Floor
New York, NY 10016

Re: *Sabol v. Bayer HealthCare Pharmaceuticals Inc., et al.*, No. 18-cv-11169
Pre-Motion Conference Regarding Planned Motion to Dismiss

Dear Mr. Burke:

Following numerous Orders to Show Cause why her Complaint should not be dismissed from the Middle District of Florida,[1] Plaintiff has re-filed her suit in New York, even though she lives in Florida, and even though she previously claimed she used Bayer's product in Florida. Defendants Bayer HealthCare Pharmaceuticals Inc., Bayer Corporation, and Bayer HealthCare LLC (collectively "Bayer") submit this letter prior to requesting that the Court hold a conference regarding a proposed motion to dismiss Plaintiff's Complaint for lack of personal jurisdiction, improper venue, and failure to state a claim.

1. Plaintiff Fails to Establish Jurisdiction or Demonstrate that This Venue Is Proper

In her Complaint, Plaintiff fails to "aver[] . . . facts that . . . establish jurisdiction over the defendant," which is necessary "to survive a motion to dismiss for lack of personal jurisdiction." *Licci ex rel. Licci v. Lebanese Canadian Bank, SAL*, 673 F.3d 50, 59 (2d Cir. 2012) (brackets and internal citations omitted). There is no general jurisdiction over Bayer since it is not headquartered or incorporated in New York. *See BNSF Ry. Co. v. Tyrrell*, 137 S. Ct. 1549, 1558 (2017) ("'paradigm' forums" of general jurisdiction are "the corporation's place of incorporation and its principal place of business"). On this point, plaintiff states that Bayer is "registered to do business in the State of New York," Compl. p.2 ¶ 9, but "an exercise of general personal jurisdiction based on registration alone would be counter to the principles of due process," *Wilderness USA, Inc. v. DeAngelo Bros. LLC*, 265 F. Supp. 3d 301, 313 (W.D.N.Y. 2017).

Specific jurisdiction over Bayer is also lacking. As pled, Bayer did nothing more than develop its MRI contrast agent product, Magnevist, that allegedly reached New York through the nationwide "stream of commerce." Compl. p.19 ¶ 93. The Supreme Court has emphasized that specific personal jurisdiction exists only where the "***defendant*** . . . ***create[s]*** contacts with the forum State." *Walden v. Fiore*, 134 S. Ct. 1115, 1126 (2014) (emphasis added). It is not enough that a defendant's "conduct affected plaintiffs with connections to the forum State," *id.* at 1126, which

[1] *See, e.g.*, Dkt. No. 49, Order to Show Cause, *Sabol v. Bayer HealthCare Pharmaceuticals Inc. et al.*, No. 8:18-cv-850 (M.D. Fla. Aug. 2, 2018).

is all Plaintiff claims by now belatedly alleging she used Magnevist in New York. Plaintiff also vaguely alleges Bayer has a New York facility and conducted in-state "clinical trials," Compl. p.2 ¶ 9, but never claims that facility involved Magnevist whatsoever or that Plaintiff's lawsuit arises from any such clinical trial.

Further, to secure transfer there, Plaintiff's counsel previously told a federal court that Plaintiff used Magnevist "within the Middle District of Florida," not in New York. *See* Dkt. No. 24, Stipulation, *Sabol v. Bayer HealthCare Pharmaceuticals Inc.*, No. 3:17-cv-6861 (N.D. Cal. March 22, 2018). Since Plaintiff's current allegation that she used Magnevist in New York is "contrary" to one she "successfully advanced in another proceeding," judicial estoppel bars her from using her new allegation to show jurisdiction. *BPP Illinois, LLC v. Royal Bank of Scotland Grp. PLC*, 859 F.3d 188, 192 (2d Cir. 2017).

Plaintiff thus fails to state "facts that . . . would suffice to establish jurisdiction," *Licci*, 673 F.3d at 59. And for similar reasons, this venue is improper. *See* 28 U.S.C. § 1391(b).

2. Plaintiff Fails to State a Claim

Complete dismissal is further warranted because Plaintiff fails to state a claim for negligence or strict liability.

A. Plaintiff's Alleged "Primary Injury" of "Gadolinium Retention" Is Not Legally Cognizable

Plaintiff's alleged "primary injury" of "gadolinium retention"—meaning trace amounts of gadolinium remained in her body without further symptoms—is not a legally cognizable injury. *See* Compl. pp.3-4 ¶ 17. New York courts have rejected claims based on mere exposure to chemicals rather than physical injury.[2] *See Caronia v. Philip Morris USA, Inc.*, 5 N.E.3d 11, 14, 19-20 (N.Y. 2013) (rejecting cigarette smokers' suit claiming exposure to "carcinogenic agents" including "tar"). *Caronia* held that "[a] threat of future harm is insufficient to impose liability against a defendant in a tort context," 5 N.E.3d at 14, 18-19, which is precisely what Plaintiff seeks to do here in alleging damages from gadolinium "retention," since that phenomenon is not itself a physical injury. *See* Compl. p.4 ¶ 18 ("Plaintiff was never warned about the ***risks*** of gadolinium retention . . . ." (emphasis added)).

B. Claims Based on Plaintiff's Other Allegations—"Fibrosis" and "Related Injuries"—Are Preempted

Claims based on Plaintiff's other alleged injuries, "fibrosis" and "related injuries," are preempted. Compl. p.10 ¶ 51. Plaintiff claims Magnevist's FDA-approved label failed to warn persons with normal kidney function of these alleged risks. To avoid preemption, Plaintiff must plead that Bayer discovered "newly acquired information" after the FDA's approval of Magnevist's label, and that this information would have allowed Plaintiff's desired label change.

[2] Since Plaintiff appears to bring her claims under New York law, Bayer will move to dismiss accordingly. Bayer reserves the right to argue that other law governs part or all of this action.

That is because "federal law expressly forbids a manufacturer from changing its label after . . . FDA approval unless such changes are made pursuant to the ['Changes Being Effected,' or 'CBE'] regulation." *Utts v. Bristol-Myers Squibb Co.*, 226 F. Supp. 3d 166, 184–85 (S.D.N.Y. 2016) (dismissing preempted claims). And "[t]he CBE procedure is only available to make changes . . . based on 'newly acquired information'" discovered after FDA approval. *In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 779 F.3d 34, 41–42 (1st Cir. 2015). The "new[]... information" must provide "reasonable evidence of a causal association" of "a clinically significant" "hazard" or "adverse reaction[]" linked to a drug. *See* 21 C.F.R. § 201.57(c)(6)(i).

Plaintiff identifies absolutely no "newly acquired information" permitting Bayer to use the CBE regulation to add her alleged risks of "fibrosis" or "related injuries" to Magnevist's label. Compl. p.10 ¶ 51. Nothing in Plaintiff's Complaint pleads "reasonable evidence of a causal association" between these alleged risks and Magnevist. *See* 21 C.F.R. § 314.70(c)(6)(iii)(A). That is unsurprising: in 2018, the FDA approved a Magnevist label stating that "clinical consequences of gadolinium retention ***have not been established*** in patients with normal renal function." *See* 7/25/2018 Revised Magnevist label at 4 (emphasis added), https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/019596s064s065lbl.pdf.[3] That is true even though ***Plaintiff's own attorney***, Todd Walburg, attended FDA meetings on this subject, ultimately failing to convince the FDA that a warning that gadolinium retention can cause clinical harm was appropriate.

C. Plaintiff Fails to Show Her Alleged Injuries Were Foreseeable

Dismissal is further warranted because Plaintiff fails to plead that Bayer could have reasonably foreseen the vague symptoms she alleges. *See Liriano v. Hobart Corp.*, 92 N.Y.2d 232, 237 (N.Y. 1998) (strict liability); *Robinson v. Reed-Prentice Div. of Package Mach. Co.*, 49 N.Y.2d 471, 480 (N.Y. 1980) (negligence). Plaintiff proclaims, with no pled facts, that Magnevist caused her "fibrosis." *See* Compl. pp.3-4 ¶ 17. That is not a side effect of Magnevist recognized by the FDA or medical community in persons with normal kidney function. *See* 7/25/2018 Revised Magnevist label p.4. Despite extensive discussion of how gadolinium may be ***retained*** in patients' bodies, the Complaint's theory of how retained gadolinium ***causes any alleged injuries*** is entirely based on patients' "advocacy groups" and "strongly worded letters" to the FDA,[4] *see* Compl. pp.15-16 ¶¶ 75-76. And Plaintiff never alleges Bayer knew of these letters or groups when she used GBCAs.[5]

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[3] Bayer will request that the Court take judicial notice of official FDA statements since they "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned," Fed. R. Evid. 201(b)(2), namely, the FDA itself. *See Canale v. Colgate-Palmolive Co.*, 258 F. Supp. 3d 312, 322 & n.9 (S.D.N.Y. 2017) (taking judicial notice of FDA action).

[4] Plaintiff's detour into a decade-old litigation over nephrogenic systemic fibrosis, a condition Plaintiff does not claim to have, does not advance her claims. *See, e.g.*, Compl. p.15 ¶ 73.

[5] Further, Plaintiff's claims provide unadorned allegations that defendants engaged in subpar "manufacture, development, production, testing, inspection, endorsement, prescription, sale and distribution" of products, and failed to warn at some time. *See* Compl. p.18 ¶ 87. These "labels and conclusions" fail to state a claim. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555, 570 (2007).

GOLDMAN ISMAIL TOMASELLI BRENNAN & BAUM LLP

Respectfully submitted,

Jennifer Greenblatt

Jennifer Greenblatt
Lead Counsel for the Bayer Defendants

cc: The Honorable Victor Marrero (By Facsimile)
United States District Judge
Southern District of New York
500 Pearl Street
New York, NY 10007

All Counsel of Record (By Email)

The Clerk of Court is directed to enter into the public record of this action the letter above submitted to the Court by the Bayer defendants as described above.
SO ORDERED.

2-26-19
DATE

VICTOR MARRERO, U.S.D.J.